Senate Committee on Environment and Public Works
Hearing Entitled, *"Hearing on the Nominations of Shannon Estenoz to be Assistant Secretary of Fish and Wildlife and Parks of the Department of Interior, Radhika Fox to be Assistant Administrator for Water of the Environmental Protection Agency, and Michal Freedhoff to be Assistant Administrator for Chemical Safety and Pollution Prevention of the Environmental Protection Agency."*
May 12, 2021
Questions for the Record for Michal Freedhoff
[VERSION SENT TO OCSPP IO MONDAY AFTERNOON]

Senator Kelly:

1. If confirmed, you would play a role in developing regulations which would govern the discharge and cleanup of PFAS. High levels of PFAS has been detected in several groundwater aquifers near Arizona military installations This is particularly concerning to me because every groundwater aquifer in Arizona could be used for drinking water – and as the Colorado River looks likely to enter a Tier 1 shortage this year, Arizona will be more dependent than ever on our groundwater supplies. If confirmed, how will you approach regulations related to PFOA and PFOS?

    a. In particular, how will you ensure that EPA supports communities that are disproportionately dependent on drinking water from closed-source aquifers?

EPA Response: As I stated at my nomination hearing, addressing PFAS and emerging contaminants will be a top priority of mine if confirmed as Assistant Administrator for the Office of Chemical Safety and Pollution Prevention.

While drinking water is not in my portfolio, EPA's chemical safety office is working on several PFAS initiatives that will help gather data and allow EPA to focus research and monitoring efforts to prioritize PFAS actions.

First, EPA is requiring any facility that releases any of almost 200 PFAS into the environment to report that to EPA under the Toxics Release Inventory and in accordance with statutory direction authored by the Senate Environment and Public Works Committee in 2019. This will help the Agency focus its monitoring and regulatory efforts.

Second, EPA has drafted a proposed rule under its TSCA authority and in accordance with statutory direction authored by the Senate Environment and Public Works Committee in 2019 that is currently undergoing interagency review that will require any company who manufactured PFAS since 2011to provide EPA information that will help focus EPA's monitoring and regulatory efforts. Specifically, EPA is proposing to request the following information on PFAS: chemical identity, production volumes, byproducts, environmental and health effects, number of individuals exposed, and manner and methods of disposal. The information gathered through this proposed rule would improve our understanding of the universe of manufacturers, categories of use, and quantities of manufactured PFAS in the U.S. This information, in turn, could help further focus the agency's PFAS research, monitoring, and regulatory efforts.

Historically, some new PFAS have been allowed to enter the market through low volume exemptions or LVEs. These requests are exempt from the full new chemical review process under TSCA and must be decided on within 30 days. Since I joined EPA, I have learned from career staff and managers that due to the scientific complexities associated with PFAS assessment, and the potential hazards of some of these chemicals, it's difficult for EPA to conduct an appropriately robust review of LVEs for PFAS in the 30 days the regulations allow. As a result, EPA recently announced that going forward we generally expect that pending and new LVE submissions for PFAS would be denied. Doing this will allow additional time to conduct a more thorough review through the PMN review process and, as appropriate, put measures in place to mitigate the potential risk of these chemicals. This approach will ensure that unsafe new PFAS are not allowed to enter into commerce.

As we continue along this process, I am committed to a flexible approach and to working collaboratively with all stakeholders on the impacts of PFAS.

2. I wanted to ask for your thoughts on the broader precedent that might be set for EPA's pesticide program from the recent court ruling in the 9th Circuit. In the 2-1 ruling, the Court superseded EPA's scientific interpretation it used to reject a petition and mandated EPA take specific regulatory actions based on the Court's scientific interpretation. I am concerned this precedent will direct how EPA must treat petitions for any chemistry moving forward. In order to withstand judicial scrutiny, EPA's career scientists may have to conduct significant reviews of all petition claims regardless of their expert assessment of the petition's underlying science. Has EPA considered these potential longer-term impacts in its decision on how to respond to the Court's ruling?

EPA Response: Chlorpyrifos is a pesticide that is known to cause neurological harm at unsafe exposure levels, and is of great concern especially to the farmworkers and their families. In their late April 2021 Opinion, the Ninth Circuit ordered EPA to revoke the tolerances for chlorpyrifos or modify them, provided that the Agency make the required safety finding. EPA is reviewing the decision and considering its options regarding its response.

As the agency pursues its mission to protect human health, including that of children, and the environment, EPA is committed to being guided by sound science as it ensures the safety of pesticides and other chemicals. The agency is committed to helping support and protect farmworkers and their families while providing important pesticide tools needed by our nation's agricultural stakeholders. **[see Cramer 1, Boozman 2]**

Ranking Member Capito:

1. The Toxic Substances Control Act (TSCA) defines "conditions of use" as the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. What is the difference between a "reasonably foreseen" use and "any possible" use?

EPA Response: EPA is committed to implementing TSCA within the statutory requirements as written by Congress.

Reasonably foreseen conditions of use are future circumstances, distinct from known or intended conditions of use, under which the chemical substance may be manufactured, processed, distributed, used, or disposed of. EPA's identification of "reasonably foreseen" conditions of use is not based on hypothetical or conjecture. Rather, the identification is necessarily a case-by-case determination, and involves application of professional judgment, experience, and discretion.

EPA indicated in its rulemaking for Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act that "the identification of "reasonably foreseen" conditions of use will necessarily be a case by case determination, and will be highly fact-specific. Sources of facts to support such determinations may include known activities associated with similar chemicals, knowledge of a chemical's properties that may allow it to replace a function currently being performed by non-chemical means, or information on research and development activities applying a chemical substance to a particular new use. It is reasonable to foresee a condition of use, for example, where facts suggest the activity is not only possible but, over time under proper conditions, probable." (82 FR 33730-31)

2. EPA evaluates potential pesticide risks under the Food Quality Protection Act, which requires a "reasonable certainty that no harm will result" from exposure to determine a pesticide is safe. Under TSCA, the risk standard is that the chemical is "not likely to present an unreasonable risk of injury to health or the environment." What is the difference in certainty between "not likely to present an unreasonable risk" and "reasonable certainty that no harm will result"?

EPA Response: TSCA and FQPA cover very different uses of chemicals and, as a result, largely different chemicals. The FQPA amended the Federal Insecticide, Fungicide and Rodenticide (FIFRA) and the Federal Food, Drug and Cosmetics Act (FFDCA) to address, among other things, setting limits on the amount of pesticides that may remain in or on foods marketed in the U.S. In contrast, TSCA covers chemical substances manufactured, processed, distributed in commerce, used or disposed of for commercial purposes in the U.S. and explicitly excludes from its purview any pesticide (as defined in FIFRA) and any food, food additive, drug, cosmetic, or device (as defined in the FFDCA). EPA is committed to implementing its programs within their statutory requirements as written by Congress. The respective risk standards, be they the Food Quality Protection Act's "reasonable certainty of no harm standard" when evaluating pesticide chemical residues on food, the TSCA standard of "not likely to present an unreasonable risk of injury to health or the environment" when considering risks from chemicals, or the "unreasonable adverse effects on the environment" standard under the Federal Insecticide, Fungicide, and Rodenticide Act in various statutes are best interpreted within their own body of regulations and policies.

3. What steps will you take to ensure transparent coordination on chemical risk assessment and management between the Office of Chemical Safety and Pollution Prevention (OCSPP) and other EPA program offices or federal agencies?

EPA Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward. If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including working with other EPA program offices and other federal agencies. OCSPP coordinates closely with other EPA Program Offices on chemical risk assessment and risk management. For chemical risk evaluation, OCSPP has (1) established a bimonthly meeting including all interested EPA Offices to update and discuss issues related to risk evaluations; (2) invited program office staff, particularly ORD staff, to join chemical risk evaluation teams for chemicals where ORD has known expertise; and (3) established an internal EPA review process with opportunities to review and comment on draft risk evaluations prior to public comment and again prior to finalization (after external peer review). Going forward, I plan to strengthen these partnerships, in particular by providing more timely interactions and allowing more time for addressing issues as they come up.

For existing chemicals in risk management, OCSPP follows EPA's processes for rulemaking, one of which is to form cross-agency workgroups that allow for input across the agency during the rule development. Additionally, we are engaging with the Occupational Safety and Health Administration, National Institute for Occupational Safety and Health, Department of Defense, National Aeronautics and Space Administration, and other federal agencies to leverage their expertise in our rule development as well as ensure that our actions do not have unintended implications for particular uses of chemical substances that are critical to the federal government. I will continue to ensure our rulemakings are informed by cross-agency expertise as well as the expertise and equities across the federal government.

4. While the Office of Research and Development (ORD) leads the Agency's scientific research activities, the OCSPP is responsible for evaluating risks from chemicals. Other EPA program offices, as well as state regulatory agencies, also carry out research and data analysis activities. Findings among different offices may not converge on a single outcome. How will you handle instances of conflicting data or conflicting conclusions within EPA or between EPA and your state partners?

EPA Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward.

In the case of TSCA existing chemical risk evaluations, all draft risk evaluations go through the internal EPA review process described in answer (3) above, providing opportunities to identity discuss and resolve differences in conclusions. Similarly, state and other external partners are afforded an opportunity to review and comment on draft risk evaluations before they are final, again providing an opportunity to identify, discuss and resolve conflicts. TSCA risk evaluations must use the best available science and a weight of evidence approach. If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including using the best available science in accordance with statutory requirements, whatever the source.

In addition, EPA has established, and continues to promote, a culture of scientific integrity for all of its employees. EPA's Scientific Integrity Policy was issued in February 2012 and provides a framework to promote scientific and ethical standards and to create a proactive culture to support them. The Policy applies to all EPA employees including scientists, managers, political appointees as well as contractors, grantees, collaborators, and student volunteers. It also describes the scope and role of a standing committee of Agency-wide scientific integrity officials to implement this policy. The policy explicitly welcomes differing views and opinions on scientific and technical matters as a legitimate and necessary part of the scientific process.

5. What do you believe is the appropriate role of the EPA's Integrated Risk Information System (IRIS) program in regulating chemicals and the risk assessment and management process, and how do you intend to ensure ORD coordination with OCSPP staff?

EPA Response: IRIS assessments are hazard assessments, not risk assessments, i.e., they do not integrate the hazard analysis with exposure information to estimate risks. TSCA risk evaluations, as mandated in TSCA section6 must "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance."
[HYPERLINK
"https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=15-USC-466989530-823698988&term_occur=999&term_src=title:15:chapter:53:subchapter:I:section:2605"]
EPA's IRIS program is a scientifically rigorous approach for assessing the human health hazards and dose-response relationships for chemicals of interest to EPA. The appropriate role of the IRIS program is to generate such chemical hazard assessments for chemicals of high priority interest to the Agency, often involving chemicals that are of interest to multiple EPA Programs and Regions. The IRIS hazard values can serve as a foundational piece of scientific information to support a variety of regulatory and risk management decisions. In the case of TSCA existing chemical risk evaluations, IRIS assessments can serve to inform the human hazard assessment for chemicals being evaluated.

Under TSCA, the Agency is required to use the best available science, whatever the source, so we routinely review and consider IRIS assessments. However, the Agency will not rely solely on IRIS assessments for its TSCA activities, as that would not be consistent with the law. Put plainly, an IRIS assessment cannot substitute for a TSCA risk evaluation.

Since arriving at the Agency, my staff and I have met frequently with our colleagues in EPA's Office of Research and Development, with a goal to re-establish and maintain a collaborative and respectful working relationship.

6. In a recent update to EPA's New Chemicals Program, EPA announced that it will no longer assume that workers are adequately protected under the Occupational Safety and Health Administration (OSHA) worker protection standards where EPA identifies a potential unreasonable risk to workers that could be addressed with appropriate

personal protective equipment and hazard communication. What empirical evidence is EPA relying on to support the new approach of no longer assuming workers are adequately protected under the OSHA worker protections standards?

EPA Response: EPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. EPA intends to ensure necessary protections for workers identified in its review of new chemicals through regulatory means. Where EPA identifies a potential unreasonable risk to workers, EPA will identify the absence of worker safeguards as "reasonably foreseen" conditions of use, and mandate necessary protections through a TSCA section 5(e) order, as appropriate. There is considerable empirical evidence that it can be reasonably foreseen that worker safeguards may not always be in place, particularly for new chemical substances that OSHA would not be aware of because they are not yet in commerce (and details of which are often confidential business information at this stage in EPA's regulatory review process). As a specific example, in 2020, violations of OSHA's respirator safety standards were the third and violations of eye and face protection were ninth in OSHA's Top 10 Most Frequently Cited Standards following inspections of worksites by federal OSHA. Please see [HYPERLINK "https://www.osha.gov/top10citedstandards"]

While it is certainly reasonably foreseeable that adequate protections for workers may not always be in place for purposes of making a determination in accordance with the statute, the Agency is aware that many companies go to great lengths to ensure the safety of their workforce.

7. A key driver for chemical innovation is to make chemicals that are safer or environmentally superior to the chemicals that they would replace.
   a. Is EPA able to evaluate whether a proposed new chemical would be safer than the chemical(s) that it would replace?
   b. If not, what prevents EPA from doing this evaluation?

EPA Response: EPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. When new chemical submitters provide information adequate for considering the unique hazard and/or exposure characteristics for a chemical believed by the submitter to be safer than alternatives, EPA can incorporate this information into the risk assessment and/or risk management decisions for that chemical. In this way, the program supports development of safer chemical substances by minimizing regulatory burdens on new chemicals if they will replace riskier substances already in the marketplace.

In addition, I plan to invest in our Safer Choice program to make safer chemicals more broadly available and help industry use safer chemicals in products. The program has an excellent track record of success and I hope to use the program to do much more -- in partnership with a broad range of stakeholders. Through the Safer Choice program, EPA's OPPT has partnered with more than 60 chemical manufacturers to evaluate their products against stringent health and environmental criteria and list EPA-confirmed safer chemicals on EPA's Safer Chemical Ingredients List (SCIL). SCIL now contains almost 1,000 chemicals that meet EPA's Safer Chemicals criteria. The chemical safety office also allows use of its Safer Choice label on products that contain only safer chemicals, meet industry performance standards, satisfy packaging requirements, and disclose ingredients. More than 400 product manufacturers now

market almost 2,000 products with the Safer Choice certification. The program is used by retailers such as Walmart and Amazon, product manufacturers large and small such as Procter and Gamble, Clorox, Reckitt, Krud Kutter, Wexford Labs, and CLR, chemical manufacturers such as BASF, and is encouraged by many states and organizations including Environmental Defense Fund, Natural Resources Defense Council, Breast Cancer Prevention Partners, and Safer Chemicals Healthy Families.

8. You have publicly stated that you plan to reopen some or all of the first ten TSCA risk evaluations of existing chemicals by looking back "surgically at specific areas in some of the risk evaluations to supplement them as appropriate." More specifically, how will your office reopen and supplement these risk evaluations, while ensuring the process is open, transparent, involves stakeholder input, and does not create undue confusion and uncertainty?

EPA Response: The Senate EPW Committee and House Energy and Commerce Committee showed leadership in passing much-needed changes to TSCA—America's primary chemical safety law. President Biden's *Executive Order 13990: Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis* requires EPA to review the last Administration actions, including risk evaluations for chemical substances under TSCA. The Agency is looking back surgically to make any needed changes in specific areas of some of the risk evaluations to make sure that the risk management rules (which must be drawn from the risk evaluations) are protective and scientifically and legally defensible. We plan to do this surgically because the first 10 risk evaluations documented unreasonable risk under the majority of conditions of use across the first ten chemicals for workers, occupational non-users, consumers and bystanders, and that already require risk management to address the unreasonable risk in order to protect human health and the environment. In some instances, however, gaps remain in the scope of the risk evaluation and so it is important to conduct additional analysis to ensure that potential unreasonable risks have not been overlooked in accordance with the law's requirements to comprehensively evaluate chemical substances. We will have new methodological approaches and any supplemental analysis subject to independent external peer review, with public comment as appropriate.

9. TSCA provides EPA 90 days to review new chemicals, or with good cause for extension, 180 days. How many submissions does EPA currently have that were submitted greater than 90 days ago? 180 days?

EPA Response: EPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. As of May 16, 2021 , EPA has 240 applications that were submitted more than 90 days earlier (and of this total, there are 189 applications that were submitted more than 180 days earlier). However, none of these applications are outside the applicable review period. EPA's regulations at 40 CFR 720.75(b) allow submitters to request a voluntary suspension of the review period, and submitters often take advantage of this option in order to develop additional data or to continue discussions about their application with EPA.

10. Under TSCA, if EPA does not conclude its review on time, EPA is required to refund all charges to the submitter. Has EPA ever issued such a refund?

EPA Response: TSCA section 5(a)(4) requires a refund of applicable fees in these circumstances, unless the submitter has not provided required information or has otherwise unduly delayed the [HYPERLINK "https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=15-USC-309518737-1298845182&term_occur=999&term_src=title:15:chapter:53:subchapter:I:section:2604"] in a way that prevents timely determination. Under such circumstances, EPA will usually grant a suspension requested by the submitter, which effectively puts the review period on "pause" to allow the submitter to provided information to EPA to clarify the initial submission or to address risk identified by EPA after the initial risk assessment is completed. EPA has on rare occasions submitted refunds for new chemical submission; for example, when a submission is deemed invalid within the first 15 days.

11. In certain circumstances, EPA can request suspensions of the TSCA deadlines and request additional information. However, EPA has been increasingly requesting suspension of the TSCA deadlines without requesting additional information. If EPA requests a suspension of the TSCA deadlines but does not request additional information, and the submitter denies the suspension request, how would EPA proceed?

EPA Response: EPA's regulations at 40 CFR 720.75(b) allow submitters to request a voluntary suspension of the review period, and submitters often take advantage of this option in order to develop additional data or to continue discussions about their application with EPA. Suspensions of new chemical reviews are requested by submitters of new chemical notices. Suspensions are most often requested when EPA has conducted an initial risk assessment for the new chemical and identified potential risks. When a submitter and EPA believe additional information may refine the risk assessment, the submitter may request a suspension to allow them time to gather or generate the information that EPA may use to refine the risk assessment.

If confirmed, I look forward to learning more about this issue from the science and programmatic experts at EPA.

12. How many suspensions has EPA requested and how many of those were not accompanied by a request for additional information?

EPA Response: EPA's regulations at 40 CFR 720.45 allow submitters to voluntarily suspend the running of the notice review period, and submitters often take advantage of this option in order to develop additional data or to continue discussions about their application with EPA. EPA has a long-standing practice of accommodating submitters requests for suspensions when submitters want to provide additional information for EPA's consideration. Please also see the response above.

If confirmed, I look forward to learning more about this issue from the science and programmatic experts at EPA.

13. Do you believe requesting the suspension without asking for additional information circumvents the deadlines in the statute?

EPA Response: I am not familiar with the specific details of EPA's practices regarding suspension of new chemical reviews or the nature and extent of new information that may be useful for refining the original assessments.

If confirmed, I look forward to learning more about this issue from the science and programmatic experts at EPA.

14. To prevent the government from slowing innovation, the previous Administration focused on reducing the backlog of new chemical applications, successfully reducing the new chemical backlog from over 450 cases to 183 cases by January 2021.
    a. What is the number of cases in the backlog today? Do you expect the backlog to increase given EPA's recently announced policy changes to new chemical reviews?
    b. How will you prevent increasing the backlog?

EPA Response: EPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. In the last Administration, EPA defined the new chemicals "backlog" in different ways at different times. See, for example, an August 2017 it was announced that the "backlog" was eliminated, although there were 302-308 cases still under review ([HYPERLINK "https://archive.epa.gov/epa/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews.html"]). As a factual matter, the number of cases under review at any given time is entirely dependent on submitter activity and fluctuates constantly. None of the cases in EPA's current queue (300 as of 5/16/2021) are outside the applicable review period. For any case that was submitted over 90 days ago, the review period has been voluntarily suspended at the request of the submitter pursuant to 40 CFR 720.75. For 73 of those 300 cases, EPA is awaiting submitter input (e.g., additional information or signature of consent order) . The remaining cases are in various stages of review, as shown on EPA's New Chemicals case tracker webpage ([HYPERLINK "https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review" \t "_blank"]). EPA remains committed to meeting statutory deadlines for review and determinations on new chemicals submissions under TSCA section 5 and will continue to engage with submitters to ensure the agency is moving as expeditiously as possible to come to a resolution on their submissions. EPA is transparent about the status of new chemical reviews by providing monthly updates regarding the status of new chemical reviews on its website: [HYPERLINK "https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review" \t "_blank"]

15. How do you plan to communicate to the public what are real-world, expected risks versus risks generated by modeling and assumptions that reflect a worst-case scenarios?

EPA Response: TSCA risk assessments include as much real-world data and information as possible.

For new chemical assessments, specific information regarding chemical manufacturing, processing and use are requisite components of the new chemical notice; however, because these chemicals are not yet being made, it is necessary to use modeling and assumptions to estimate exposures and releases. In addition, because TSCA does not have upfront testing requirements, EPA uses predictive models and other computational methods to conduct chemistry, environmental fate and hazard components of new chemical risk assessments. However, EPA will always consider and use real-world data should submitters provide it and it reflects best available information.

For existing chemicals, the statutorily required prioritization, scope and risk evaluation stages of risk evaluation each provide opportunities for EPA to request or require from those with knowledge and in possession of real-world data to provide it to EPA for use in risk evaluations. Furthermore, EPA routinely includes multiple scenarios and assumptions (e.g., central tendency), not only high-end or worst-case scenarios in its risk evaluations.

In addition, EPA has begun to use its data gathering authorities to support acquiring such real-world data for existing chemicals. For example, in February of this year, the chemical safety office issued TSCA section 4 test orders to collect real-world occupational exposure data and develop new fate and toxicity data for 9 of the chemicals currently undergoing risk evaluation and additional test orders are being developed. In addition, in April, at the recommendation of the Inter-agency Testing Committee, 50 chemicals were added to the TSCA Section 4(e) Priority Testing List, which includes chemicals to be given priority consideration for the development of information under TSCA section 4(a) using rules, orders, or consent agreements, as appropriate. In addition, a TSCA section 8(d) rule will be issued very soon for the purpose of collecting existing health and safety data for these 50 chemicals, some of which are chemicals currently undergoing TSCA risk evaluation.

All of these activities to collect data and information will enhance and inform real world scenarios in risk evaluations. This information is used in the risk evaluation, in accordance with EPA's Information Quality Guidelines, and allows the Agency to more accurately estimate the upper-bound, central, and lower-bound estimate of risk for a given exposed population, including those populations that are more susceptible. If confirmed, I commit to further exercising TSCA section 4 and 8 authorities to collect real-world data and information to support chemical assessment and management under TSCA. I also commit to pursuing addition of chemicals on the 2014 TSCA Work Plan to the Toxics Release Inventory (TRI), as this data is routinely used in TSCA risk evaluations.

I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA. As I said in my response to Chairman Carper related to worker safety, I also believe that the Agency could improve upon its TSCA risk communications efforts in order to provide the appropriate context for its risk evaluations, and if confirmed, I commit to making that a priority.

16. In a previous conversation with me, you acknowledged that not all PFAS are the same. Do you think EPA should analyze and regulate individual PFAS based on their particular health and environmental risks?

EPA Response: President Biden highlighted the importance of and his commitment to tackling PFAS pollution and protecting human health and the environment. If confirmed, I am committed to addressing PFAS as a top priority for EPA.

Consistent with TSCA, the chemical safety office assesses and regulates PFAS either individually or as groups/categories based on similarity in physical-chemical and biological properties, as deemed appropriate based on the availability of data/information and the regulatory context and decision being made. Grouping or category approaches for chemical assessment and regulation have been used under TSCA for both new and existing chemical assessment for decades.

In the legislative language authored by the Senate Environment and Public Works Committee and enacted in 2019, the Agency (through its Office of Research and Development, ORD) was given direction to

> *"(2) develop a process for prioritizing which perfluoroalkyl and polyfluoroalkyl substances, or classes of perfluoroalkyl and polyfluoroalkyl substances, should be subject to additional research or regulatory efforts that is based on—*
>
> *(A) the potential for human exposure to the substances or classes of substances;*
>
> *(B) the potential toxicity of the substances or classes of substances; and*
>
> *(C) information available about the substances or classes of substances;"*

My office sees great value and near-term applicability of ORD's work in this area. In fact, currently my office is working collaboratively with ORD in considering the development of a national PFAS testing strategy that is based on ORD's research framework for grouping PFAS into sub-classes or categories coupled with using our TSCA data-gathering authorities to augment these efforts and fill identified information gaps. Working together, we believe such the strategy will be both scientifically sound and useful to inform the Agency's monitoring and regulatory efforts for PFAS.

17. Should PFAS ever be grouped and reviewed accordingly based on similar physical, chemical, and biological properties and, if so, what scientific reviews are necessary to ensure that a group of PFAS compounds pose the same health and environmental risks, if any?

EPA Response: President Biden highlighted the importance of his commitment to tackling PFAS pollution and protecting public health and the environment. If confirmed, I am committed to addressing PFAS as a top priority for EPA.

In the legislative language authored by the Senate Environment and Public Works Committee and enacted in 2019, the Agency (through its Office of Research and Development, ORD) was given direction to

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>
> *(A) the potential for human exposure to the substances or classes of substances;*
>
> *(B) the potential toxicity of the substances or classes of substances; and*
>
> *(C) information available about the substances or classes of substances;"*

This language indicates that the potential for exposure, toxicity and information available for PFAS may be based on individual *substances* or *classes of substances.* Generally, classes or sub-classes of substances are groupings based on similar structural, physical-chemical and/or biological properties.

The chemical safety office believes that grouping of PFAS based on similarity in structural, physical-chemical and biological properties is appropriate. Further, such grouping or category approaches have been used within OPPT for both new and existing chemical assessment for decades. This experience, and the emerging research conducted by ORD (as directed by SEPW), as well as established approaches, for example as developed in the Organization for Economic Cooperation and Development (OECD), for developing scientifically sound chemical groups or categories, would be the basis for ensuring PFAS groups or categories are scientifically sound.

18. During your nomination hearing before the Committee, you acknowledged that there are gaps in EPA's PFAS research that need to be filled. What are the remaining PFAS research gaps that need to be resolve before the Agency is able to move forward with additional regulatory actions?

EPA Response: President Biden highlighted the importance of and his commitment to tackling PFAS pollution and protecting public health and the environment. If confirmed, I am committed to addressing PFAS as a top priority for EPA.

Generally, all of EPA's regulatory statutes require the Agency to be able to characterize the health and/or environmental effect of a substance (or category of substances) to determine whether to regulate that substance (or category of substances), and to be able to measure the substance (or category of substances) in the air, water, or soil in order to promulgate an implementable and enforceable regulation. While extensive research exists for some PFAS substances, that is not the case for all of them. The efforts underway at EPA that draw in part from legislation authored by the Senate Environment and Public Works Committee are designed to strategically focus our research, monitoring and regulatory efforts on the PFAS that have been

identified as being of concern due either to their potential hazard or presence in the environment (e.g., research described in #15 above and TSCA data gathering activities described in response to Senator Kelly).

19. What is a simple chemical description that is common to and describes all PFAS compounds?

EPA Response: President Biden highlighted the importance of and his commitment to tackling PFAS pollution and protecting public health and the environment. If confirmed, I am committed to addressing PFAS as a top priority for EPA.

Although there is no universally accepted definition, we are all aware that per- and polyfluoroalkyl substance are a large and complex group of chemicals with thousands of variations. For the purposes a several rulemakings under TSCA, the technical structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R'' where both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen, has been used. It should be noted that this structural definition of PFAS which has been developed for the purposes of these TSCA rules is a working definition which has been used by EPA's Office of Pollution Prevention and Toxics when identifying PFAS on the TSCA Inventory (this definition may not be identical to other definitions of PFAS used within by EPA and/or other organizations).

EPA is also participating in an effort underway organized by the Organization for Economic Cooperation and Development (OECD) and the United Nations Environment Programme (UNEP) to review the existing universe of PFAS terminology and provide recommendations and guidance to stakeholders regarding PFAS terminology. When final, EPA will consider this guidance and applicability to TSCA regulatory programs.

20. Given this Administration's policy of evidence-based decisions supported by the best available science and data, how would you handle a situation where staff work relies on a scientific study that is missing critical information to support its findings?

EPA Response:

OCSPP uses Systematic Review to search and evaluate the quality and completeness of scientific studies used for TSCA Risk Evaluations, consistent with current standards of best available science. Through this review, EPA evaluates the quality of scientific studies and other evidence which allows for an objective weighing of all scientific evidence to serve as the basis for the risk evaluation. Furthermore, use of systematic review methods and techniques allows EPA to rigorously identify existing information and identify of gaps in information. For example, the scopes for the 20 risk evaluations initiated in December 2019 include "literature invntorv "trees" and "heat maps" that identify reasonably available information. Gaps in information can be filled through TSCA related- related information gathering options such as Section 4 test orders; or gaps can be addressed through a variety of modeling approaches. The resulting risk evaluation, including the assessment of the underlying body of evidence, is subject to a rigorous external and independent peer review to ensure that the results meet the bar of best available science.

In addition, TSCA risk evaluations are subjected to public comment, which presents an opportunity to submit studies that commenters believe the Agency has overlooked or concerns with our use of specific studies.

If confirmed, I will ensure this Protocol is published for public comment and peer reviewed. I also commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including relying on the best available science.

Senator Inhofe:

1. Dr. Freedhoff, as EPA continues implementing the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, it is fundamentally important that the EPA safeguard private stakeholders' confidential business information. Protecting America's confidential business information is vital to global competitiveness and national security. We cannot allow countries like China access to sensitive business information. Will you ensure the regulated community has ample time to ask questions and make corrections to any sensitive business information that will be shared publicly by EPA?

EPA Response: EPA is committed to transparency the protection of legitimate confidential business information as part of its responsibilities under TSCA. Under TSCA, EPA collects a range of information and in some cases the law allows some of the information to be claimed as confidential business information (CBI). EPA takes seriously its statutory obligation to review and protect properly substantiated CBI claims, and realizes the release of legitimate CBI may cause substantial business injury to the information owner.

EPA has established new processes, systems, and procedures to enable TSCA submitters to provide the information required when making confidentiality claims and to facilitate EPA's review, and where applicable, determinations on these claims. This activity was mandated by the 2016 amendments to TSCA.

In April 2021, the Agency posted a list of 390 chemicals by accession numbers expected to lose confidential chemical identity status and be moved to the public portion of the TSCA Inventory. Stakeholders were initially given a deadline of May 14, 2021 to notify the agency of any possible errors on the list. In response to industry stakeholder requests for additional time to review this list, EPA recently extended the notification deadline to June 30, 2021.

All of these chemicals were reported in the TSCA section 8(b) Chemical Data Reporting (CDR) rule during the CDR collection periods for 2012, 2016 and/or 2020 data and the identity was not claimed as confidential by at least one manufacturer. By not claiming the chemical as confidential, it is no longer a secret that the particular chemical is in U.S commerce. The agency also did a "hands on" review of each individual report in which the system reflected that confidential status was not requested for each of the 390 chemicals identity.

TSCA requires that the agency balance transparency, the public right-to-know, with a long-understood, and embraced, responsibility to protect confidential business information. A manufacturer has a right to waive, or release a confidential business information claim, and may want to, for example, when: (1) the chemical identity may be known to be in US commerce and therefore the confidential chemical identity status could no longer be legally withheld, (2) the chemical identity may not now be viewed by the company as sensitive for a variety of reasons and/or (3) the company may see actual commercial advantage in releasing the chemical name in its products and to the public.

2. Dr. Freedhoff, it is fundamentally important that the EPA continually engage the private stakeholders it is regulating. As you know, the EPA is currently conducting a public comment period on five final rules for persistent, bioaccumulative toxic chemicals previously issued on January 6, 2021, under TSCA. I am aware of concerns that these rules may pose challenges for retailers, who are newly subject to potentially strict liabilities and high penalties for the sale of "articles" containing these chemicals. However, it is my understanding that these rules may not provide retailers with the information they need to take action related to these articles. Has EPA conducted outreach to the retail community to seek their input on the best way to enable their participation in these new rules?
   a. Will you commit to working with retailers to ensure they are provided with the supply chain information they need to implement the intended sales restrictions on articles?
   b. And will you commit to improving stakeholder engagement as you continue implementation of TSCA?

EPA Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward. If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA.

Regarding the rules for persistent, bioaccumulative and toxic (PBT) chemicals that were finalized by the last Administration, I commit that before making a decision on next steps, EPA will review public comments received in response to the Agency's request for comment on the final PBT rules. I have personally met with stakeholders that have articles in their supply chains. For example, I have met with the Consumer Technology Association (CTA), Chemical Users Coalition (CUC) (twice), IPC Association Connecting Electronics Industries (IPC), Information Technology Industry Council (ITI), National Association of Manufacturers (NAM), National Association of Music Merchants (NAMM), National Electrical Manufacturers Association (NEMA), and the Semiconductor Industry Association (SIA). Additionally, my staff have met with many of these same stakeholders as well as others such as the Aerospace Industries Association (AIA) to continue to engage on regulated entities that have complex supply chains in order to educate and discuss their supply chain challenges.

As I noted in response to a question from Senator Kelly, from a process perspective, I believe that the Trump Administration made every effort to engage all stakeholders as it developed and

finalized these rules, and it came as a surprise to me and EPA career staff when we learned that many stakeholders were apparently unaware of these Rules' applicability on their activities. I have personally told industry stakeholders that I would welcome their ideas for how the Agency can more effectively communicate with stakeholders in the future, and if confirmed, I am committed to making such communications a priority.

3. Dr. Freedhoff, there are a number of measures that we must take to eradicate the COVID-19 pandemic. Vaccinations are an important and effective measure against the virus but there are additional measures that can be utilized to reduce the spread of COVID-19, including through long-lasting disinfectants. Long-lasting disinfectants minimize the required number of regular disinfectant applications, thereby reducing the potential negative health impacts that come from over application of regular disinfectants. Allied BioScience (ABS), a biotech firm, created "SurfaceWise2", which is a continuously active antiviral surface coating that kills viruses, including SARS-CoV-2. Accordingly, ABS has submitted an application for nationwide use of the product under the standard authority laid out in Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). If approved for use, Americans would have access to a long-lasting disinfectant that has been approved by EPA for residual efficacy of up to 30-days. When do you expect the final Section 3 approval process to be completed?
   a. Are there any steps you can take to expedite the regulatory review process?
   b. And will you please keep my staff updated on EPA's review and actions related to this application?

EPA Response: In order to respond to the public's needs over this past year of the pandemic, EPA expedited review and approval of surface disinfectant products for use against SARS-CoV-2, the coronavirus that causes COVID-19, creating and then adding over 500 products to EPA's list of disinfectants entitled List N. Over the course of the last year, EPA reacted to unprecedented circumstances by activating its Emerging Viral Pathogens guidance, minimizing disinfectants supply chain disruptions through regulatory flexibilities, releasing new and updated scientific protocols, and providing several pathways for expedited review. EPA will continue to follow the evolving science of the pandemic by shifting resources to the evaluation of novel products, such as those that kill airborne SARS-CoV-2, and to meeting critical deadlines in the registration and review of all pesticide products within its purview.

In 2020, the agency issued emergency approval of Allied BioScience's novel surface coating based on requests from Texas, Oklahoma, and Arkansas. Allied BioScience submitted an application to the agency in February 2021 for a section 3 FIFRA registration so that the technology could be used nationwide and added to the List of approved COVID-19 disinfectants (List N Appendix; Supplemental Residual Antimicrobial Products). The science regarding the efficacy of the company's novel surface coating continues to be evaluated. The due date to complete the review for this registration is August 2021 and the agency has been in regular communication with the registrant on its application. I commit to keeping Congress informed on EPA actions, including communicating with your office regarding Allied BioScience's application for their SurfaceWise2 product.

Senator Cramer:

1. Dr. Freedhoff, North Dakota is home to the most innovative and resilient agricultural producers. These producers operate on tight margins in order to provide the highest quality food, fuel, and fiber in the world. Unfortunately, producers are reluctant to commit to long-term purchases of chemical products because of the fear that the products or components could be revoked or altered at any time, leaving them with purchased product they are unable to use. The agricultural community has expressed a strong interest in the Environmental Protection Agency (EPA) maintaining an independent, predictable, science-based, and risk-based regulatory process for pesticides that generates continuity and reliability for their operations. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Congress granted EPA the authority to determine pesticide safety. EPA's Office of Pesticide Programs is staffed by scientists that work to ensure each registration label is underpinned by sound science with respect to human health and the environment. You are no doubt aware of the recent ruling in LULAC v. EPA. I am concerned the potential precedent this ruling might set and the impact it may have on EPA's pesticide program. If a court can place its own scientific interpretation over EPA's, that could undermine EPA's authority to make independent, science-based decisions, and might require EPA to invest significant resources to review petition claims in the future to ensure decisions withstand judicial scrutiny.
   a. Is EPA concerned about the potential of this precedent and considering potential long-term impacts in its response to the ruling?
   b. Should the frequency of petitions increase or if EPA must invest additional staff work into their consideration moving forward, does EPA have the capability to conduct additional petition work without significant disruptions to the pesticide program?
   c. How will you work with EPA's Office of General Counsel and the Justice Department to defend the science behind existing pesticide registrations, of which EPA career scientists within the Office of Pesticide Programs work to underpin with sound science?
   d. Do you believe the pesticide program should be stable and predictable?
   e. Should you be confirmed, how will you work with producers and industry to provide certainty and consistency to the pesticide program?

EPA Response: Chlorpyrifos is a pesticide that is known to cause neurological harm at unsafe exposure levels and is of great concern especially to the farmworkers and their families. In their late April 2021 Opinion, the Ninth Circuit ordered EPA to revoke the tolerances for chlorpyrifos or modify them, provided that the Agency make the required safety finding. EPA is reviewing the decision and considering its options regarding its response.

EPA believes it is important to be responsive to petitions from the American public where there may be concerns regarding the safety of specific pesticide products. To respond to these concerns, EPA relies on the best available science and makes every effort to integrate our responses to petitions with our ongoing work under the registration and registration review programs.

EPA will continue to use sound science in all decision-making processes under the Federal Insecticide, Fungicide and Rodenticide Act and Federal Food Drug and Cosmetic Act, and we

rely on the science developed by our career staff, in working with EPA's Office of General Counsel and the Justice Department, to defend these decisions.

Providing predictability on pesticide regulatory decisions is an important goal of the pesticide program. The Pesticide Registration Improvement Act (PRIA) provides a registration service fee system for applications for specific pesticide registration actions, which is designed to create a more predictable evaluation process for affected pesticide decisions. Regulatory decisions based on sound science is central to achieving this predictability. Moreover, I am committed to engaging with all stakeholders, to listen to their concerns, and to work collaboratively with them to enhance the robustness and certainty of the pesticide program. Since arriving to EPA, I have met with various agricultural stakeholders, including CropLife America and the American Soybean Association, to better understand their concerns and priorities, and will continue to do so.

As the agency pursues its mission to protect human health, including that of children, and the environment, EPA is committed to ensuring the safety of pesticides and other chemicals. The agency is committed to helping support and protect farmworkers and their families while ensuring pesticides are used safely among the nation's agriculture. **[see Kelly 2, Boozman 2]**

2. Dr. Freedhoff, as you know in 2016 Congress reformed TSCA on a bipartisan basis. I played a role in this from serving on the House Energy and Commerce Committee. At the time, it was viewed as a win-win for human and environmental health and timely review for product innovations by businesses. Significant fees are now assessed on industry in return for commitments on adequate staffing for efficient reviews. However, it is being reported that implementation of the 2016 reforms has been bumpy and is getting even bumpier at EPA. Chemical reviews have stalled, staff are unable to have meaningful dialogue with industry, extreme assumptions on risk are being made, and the best available science and real world data is not being incorporated. As a result, U.S. innovation is being stifled, putting American manufacturing at a competitive disadvantage.
   a. Are you committed to work with industry to get a clear, consistent, and timely process?

EPA Response: The Senate EPW Committee and the House Energy and Commerce Committee showed leadership in passing much-needed changes to TSCA—America's primary chemical safety law. President Biden's *Executive Order 13990: Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis* requires EPA to review the last Administration actions, including risk evaluations for chemical substances under TSCA.

If confirmed, I will work with all stakeholders, including industry, to implement strong chemical safety protections with a much-needed emphasis on safeguarding workers who manufacture or handle chemicals and reducing the potential disproportionate impact such chemicals have on people of color and low-income and indigenous communities.

I am committed to working with all stakeholders, including industry, to get a clear, consistent, and timely process. Since arriving at the Agency, I have met with numerous industry groups,

and have repeatedly expressed my commitment to ensuring that the chemical safety office solicits industry data and other information, incorporates that information into our decision-making, and works to address industry concerns wherever possible.

OSCPP staff meet regularly with external stakeholders including industry groups to discuss information gathering efforts and to become informed about other sources of stakeholder input such as peer reviewed studies or other data sets which can be made available. Similarly, EPA staff regularly convene pre-notice meetings with new chemical submitters to answer questions regarding submission of notices and they continue to work with the submitter throughout the new chemical review process to obtain clarification on the information submitted, share preliminary finding of the risk assessment and work with submitters to develop effective and workable risk management approaches when solutions when EPA finds the new chemical 'may present unreasonable risk' that require issuance of a TSCA section 5(e) order. Additionally, OCSPP staff leading rulemakings are meeting with industry stakeholders and other interested parties to ensure that the rules under development will be protective and practicable.

As I also said in my response to Chairman Carper related to worker safety, I believe that the Agency could improve upon its TSCA risk communications efforts in order to provide the appropriate context for its risk evaluations, and if confirmed, I commit to making that a priority.

Senator Lummis:

1. Does the EPA plan to alter existing or establish new mineralogical definitions? If so, will you commit to obtaining and incorporating input from mineralogical experts?

EPA Response: If confirmed, I commit to conducting my office's work in a transparent and scientifically rigorous manner. This will include public consultations with independent advisory bodies such as the Science Advisory Committee on chemicals (SACC), as well as soliciting and incorporating external expertise via a public comment and peer review for key analyses such as TSCA existing chemical risk evaluations. For example, EPA is committed to moving forward with a risk evaluation for legacy uses of asbestos which is a mineral existing in multiple forms. The definition of asbestos will be documented in a scoping document which will be developed through a systematic review of evidence and subject to public comment, and the risk evaluation itself will eventually be subjected to both public comment and independent external peer review. It is through these mechanisms that EPA will obtain input from external experts and will consider that input as EPA finalizes our assessments.

If there are other mineralogical definitions which are of interest to you, please let me know and I commit to follow up with a more detailed response.

I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including working with regulated entities. EPA will continue to use sound science in the decision-making process under our chemical safety programs and to implementing those programs within their statutory requirements as written by Congress, including as we consider mineral forms such as in asbestos.

2. At your nomination hearing, you emphasized that EPA's decision-making will be transparent and well-documented. Do you commit to provide the same level of transparency and documentation to regulated entities throughout the risk evaluation and management process, including engaging with those entities while developing draft risk evaluations?

EPA Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including working with regulated entities.

Since arriving at the Agency, I have met with numerous industry groups, and have repeatedly expressed my commitment to ensuring that the chemical safety office solicits industry data and other information, incorporates that information into our decision-making, and works to address industry concerns wherever possible. This transparency and documentation will be extended to all stakeholders, including regulated entities.

For risk evaluations, OCSPP will continue the practice of meeting with stakeholders at their request, including regulated entities, to discuss areas of interest and to receive information on data and analyses which they may provide. When information is shared it will be added to the body of evidence which is subjected to systematic review and made available to the risk evaluation teams. Draft risk evaluations will be shared with all stakeholders including regulated entities via a public comment process, and responses to all comments received will be made public via a docket.

For the risk management actions we intend to take, EPA recognizes the importance of substantial engagement from all stakeholders, including industry and the communities impacted by the chemicals we have evaluated. Engagement is especially critical because this is the first time we will be using the authorities under TSCA to address unreasonable risks identified in the risk evaluations. In addition to the formal processes established to consult with small businesses, tribes, State and local governments, and environmental justice advocates, we have sought and will continue to seek input from all stakeholders on potential risk management approaches, and the effectiveness and impacts of those approaches.

3. A lack of clear risk communication by EPA frequently creates public concerns over health and safety, many of which are the result of lack of information as opposed to actual risk to human health or the environment. What role does public perception play in EPA's decision-making?

EPA Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA.

As I also said in my response to Chairman Carper related to worker safety, I believe that the Agency could improve upon its TSCA risk communications efforts in order to provide the appropriate context for its risk evaluations, and if confirmed, I commit to making that a priority.

Senator Boozman:

1. The 2018 farm bill directed the Environmental Protection Agency (EPA), the Department of Interior's Fish & Wildlife Services, and the Department of Commerce's National Marine Fisheries Services ("Services") to establish an Interagency Work Group (IWG) to increase the timeliness and quality of Endangered Species Act species and habitat consultations for pesticides, develop a streamlined process for identifying which actions require consultations, and secure durable cooperation between the agencies. In recent public statements you said fixing the alignment of the Endangered Species Act (ESA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is essential and if not fixed, will put EPA's ability to approve new crop protection products at risk to being shut down by the courts. If confirmed, do you commit to spending the time and energy it will take to work with your colleagues at the Services to substantially improve the ESA-FIFRA process, so that timely registration of crop protection products is more certain?
   a. If so, what are the three most important administrative reform ideas you plan to pursue?
   b. Do you support using the best available data and analyzing "what's likely vs. what's possible" when considering rates of use of pesticides?

EPA Response: I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting endangered species and supporting local agricultural economies.

However, we also need to make further progress in making endangered species effects determinations in a more efficient manner and based on sound science. While we will continue to work and consult with the Services, as appropriate, and meet our litigation related commitments, EPA is beginning an effort to identify and implement protections for listed species earlier in the pesticide registration process. To that end, EPA is interested in working with its stakeholders, particularly the registrants and growers, to identify mitigations for protecting species in the short term. The Agency believes this is an area where the concept of conservation measures might be helpful. I have also encouraged pesticide manufacturers to continue efforts to develop newer reduced risk chemistries and challenged them to actively consider environmental effects to endangered species as part of the process.

EPA is committed to working with its stakeholders to realize our shared goal of protecting vulnerable species in a manner that is both effective and practical and ensures the availability and benefits of pesticides.

If confirmed, I look forward to working with the agricultural community and other stakeholder groups on how to chart a path forward.

2. It is essential for EPA to maintain an independent, predictable, science-based, and risk-based regulatory process to ensure the safety and efficacy of pesticides. EPA's Office of Pesticide Programs is staffed by expert scientists that work to ensure each registration label is underpinned by sound science with respect to human health and the environment. Unfortunately, the U.S. Court of Appeals for the Ninth Circuit has increasingly supplanted EPA's registration and registration review decisions instead of relying on the scientific analysis of EPA's career scientists. An example is the recent decision by the U.S. Court of Appeals for the Ninth Circuit issued on April 29, 2021, in the case of *League of United Latin American Citizens, et al. v. U.S. Environmental Protection Agency* concerning chlorpyrifos and other recent registrations undergoing legal challenge including glyphosate. In your view does the Ninth Circuit's increasing interest in renegotiating registrations from the bench pose as a threat to EPA scientific integrity, the work of its Office of Pesticides Program career staff, and EPA's existing registration processes?
   a. If confirmed, how will you work with EPA's Office of General Counsel and the Department of Justice to defend the Agency's science-based decisions on existing pesticide registrations?

   EPA Response: Chlorpyrifos is a pesticide that is known to cause neurological harm at unsafe exposure levels, and is of great concern especially to the farmworkers and their families. In their late April 2021 Opinion, the Ninth Circuit ordered EPA to revoke the tolerances for chlorpyrifos or modify them, provided that the Agency make the required safety finding. EPA is reviewing the decision as it considers its options regarding its response.

   As the agency pursues its mission to protect human health, including that of children, and the environment, EPA is committed to ensuring the safety of pesticides and other chemicals. The agency is committed to helping support and protect farmworkers and their families while ensuring pesticides are used safely among the nation's agriculture. EPA will continue to use sound science in the decision-making process under the Federal Insecticide, Fungicide and Rodenticide Act. **[see Kelly 2, Cramer 1]**

3. The Pesticide Registration Improvement Act was signed into law in 2004 and was reauthorized in 2007, 2012 and 2019 – each time with the support of a diverse consortium of trade associations, non-governmental organizations, and state government officials. This legislation brought new, dedicated funds to the Environmental Protection Agency's Office of Pesticide Programs for more efficient pesticide registration and re-registration activities; it gave registrants certainty in the registration process after decades of uncertainty; it provided funding for farm worker education and training; and it brought needed funds for training for agricultural and healthcare workers. Over the past few years, due to resource constraints and other issues, the rate in renegotiated decision

timeframes for pesticide regulatory reviews has increased significantly. Since the start of the fiscal year, EPA has renegotiated nearly 64% of all conventional pesticide decision deadlines, 24% of biopesticide decision deadlines, 6% of antimicrobial deadlines and over 28% of inert ingredient decision deadlines. In addition, there is a significant backlog of smaller non-PRIA actions that are paid for by annual registrant maintenance fees on existing products. If confirmed, will you work to enact process improvements to address the significant renegotiation rates and the backlog of non-PRIA actions?

a. Further, if confirmed, will you continue efforts of past Assistant Administrators and convene all stakeholders including Congress, industry and the NGOs community with the goal of reauthorizing PRIA prior to October 1, 2023 to ensure EPA has the resources to complete timely pesticide registration and registration review decisions as efficiently as possible?

EPA response: I agree and, if confirmed, will continue efforts to work with stakeholders and Congress to provide technical assistance to support the successful reauthorization of PRIA, to ensure EPA has the needed resources to accomplish its mission, and provide a more predictable evaluation process for affected pesticide decisions. PRIA is vital to the agency, which not only authorizes the collection of fees for various pesticide registration actions, but also funds other stakeholder priorities, such as farm worker protection activities, partnership grants, and pesticide safety education programs.

4. EPA has an essential role in facilitating trade through harmonizing U.S. pesticide tolerances with Codex Maximum Residue Levels in the registration review process to renewing the Trilateral Working Group on pesticides under the Sanitary/Phytosanitary Committee on the new USMCA agreement. Importers of pesticide products manufactured in the U.S. require submission of both certificates of origin and certificates of registration issued by EPA, a process that needs improvements before it becomes an unnecessary trade barrier. If confirmed, do you commit to facilitating international trade for the industries regulated by EPA, including crop protection?

EPA Response: If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including working with other countries and international organizations.

I support EPA's risk-based approaches to pesticide assessments. EPA's risk-based approach to pesticide regulation considers both hazard and potential exposure, with a rigorous risk assessment and risk management process. To this end, EPA's continued work with Canada and Mexico, now under the USMCA agreement, is important in developing harmonized approaches across North America. Moreover, EPA continues to collaborate with international pesticide regulators on global joint reviews of new active ingredients and in other forums to understand and potentially resolve differences in assessment and regulatory approaches.

If confirmed, I would look forward to being further briefed on issues such as this related to improving EPA's pesticides programs and international trade.

5. In December 2020, the Mexican government issued a Presidential Decree stating the intent to eliminate the use, distribution, and importation of glyphosate in Mexico. The Decree, which is inconsistent with the U.S.-Mexico-Canada Agreement (USMCA), sound science, and other international sanitary/phyto-sanitary (SPS) standards, creates a dangerous potential precedent that could extend to other agricultural chemicals and negatively impact U.S. agricultural exports. If confirmed, do you commit to working with USTR and USDA to ensure our trading partners uphold their commitments, including scientifically sound SPS standards, related to crop protection tools under our trade agreements?

EPA Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including working with other federal agencies, countries, and international organizations.

I support EPA's risk-based approaches to pesticide assessments. EPA's risk-based approach to pesticide regulation considers both hazard and potential exposure, with a rigorous risk assessment and risk management process. To this end, EPA's continued long-standing work with Canada and Mexico, now under the USMCA agreement, is important in developing harmonized approaches across North America. Moreover, EPA continues to collaborate with international pesticide regulators on global joint reviews of new active ingredients, and with USDA and USTR in other forums to understand and potentially resolve differences in assessment and regulatory approaches.

If confirmed, I would look forward to being further briefed on issues such as this related to improving EPA's pesticides programs and international trade.

6. On August 31, 2020, EPA published a proposed rule in the Federal Register (EPA-HQ-OPP-2019-0508) [HYPERLINK "https://www.epa.gov/sites/production/files/2020-09/documents/10014-10-prepub-fr-doc-admin_esignature2020-08-31.pdf" \h], which was written by EPA career experts in the Office of Pesticide Programs' Biopesticides and Pollution Prevention Division. During the rule's subsequent 60 day public comment period, agricultural and technology stakeholders welcomed EPA's efforts to facilitate a more streamlined, science-based regulatory pathway for this technology, and those stakeholders provided targeted recommendations on ways to improve the proposed rule. Finalizing this rulemaking, consistent with the aforementioned stakeholders recommendations, would help modernize EPA's regulatory approach to these technologies that could result in less water usage, less crop and food waste, and help combat climate change. Without this rule, there is not a consistent, workable regulatory pathway for these technologies. If confirmed, do you commit to ensuring EPA submits a final rule to the Office of Information and Regulatory Affairs at the Office of Management and Budget for interagency review as soon as possible?

EPA Response: If confirmed, I look forward to working with colleagues at the U.S. Department of Agriculture on these issues, and more broadly, to working with stakeholders to run our pesticides programs taking into account new technologies and innovations. In October 2020, in response to newer technologies and the policy goals of multiple administrations, EPA proposed a rule to exempt certain plant-incorporated protectant products – or PIPs – from regulation under FIFRA and FFDCA due to their low risk, as PIPs developed through biotechnology that are equivalent to the low-risk PIPs developed through conventional breeding that are already exempted. This continues to be an agency priority, as highlighted in EPA's regulatory agenda, and we are currently considering the comments received on the proposed rule with goal of responding and issuing a final rule later this year.

7. EPA's pesticide evaluation process is science-based and considers both the potential risks *and* benefits of pesticide products. The registration process includes risk assessments to ensure a product protects human health, including the health of children, the elderly, and immune-compromised individuals, the environment, and endangered species. Further, under the law EPA must reevaluate all registered pesticides at least every 15 years to ensure they continue to meet required safety standards. The current review cycle concludes October 1, 2022. This robust –science-based regulatory system is essential to providing consumers with assurance about the safety of pesticide products that are vital in protecting our nation's food supply, public health and safety, infrastructure, natural resources, and green spaces. Our regulatory process is also seen as the gold standard for the world and is required to meet World Trade Organization obligations. If confirmed, how will EPA strengthen and defend risk-based regulation and the science supporting its regulatory decisions?

EPA Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward.

I support EPA's risk-based approaches to pesticide assessments. EPA's risk-based approach to pesticide regulation considers both hazard and potential exposure, with a rigorous risk assessment and risk management process. To this end, EPA's continued work with Canada and Mexico, now under the USMCA agreement, is important in developing harmonized approaches across North America. Moreover, EPA continues to collaborate with international pesticide regulators on global joint reviews of new active ingredients and in other forums to understand and potentially resolve differences in assessment and regulatory approaches.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including our pesticides programs.

8. Pests are harmful to our nation's food supply, public health, infrastructure, natural resources, and green spaces. Science-based integrated pest management (IPM) programs are used to manage mosquitoes, ticks, and rodents that carry disease; protect our nation's

public utilities, rights-of-way, and infrastructure from invasive weeds; manage overgrowth and vegetation that pose fire hazards; and maintain homes, greenspaces, parks, sports fields, and golf courses. The definition of IPM is contained in three federal laws: (1) the 1996 Food Quality Protection Act (PL 104-170); (2) the Children's Health Act of 2000 (PL 106-310); and (3) the Food, Conservation, and Energy Act of 2008 (PL 110-234). These laws define IPM as "a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks." IPM tries to reduce the risk of pests becoming a problem in the first place while having a specific plan of action to follow when pest populations reach a certain level. In the school environment, for example, this tolerance level may be quite low, or even "zero," in the case of rodents in school cafeterias. If confirmed, will EPA uphold the statutory definitions of IPM and ensure *all* essential pest control tools – biological, cultural, physical, and chemical – continue to be available to consumers, professionals, and those that maintain facilities such as schools, parks, athletic fields, day care centers, hospitals, and residences?

EPA Response: As the agency pursues its mission to protect human health and the environment, EPA is committed to ensuring the safety of pesticides and other chemicals. EPA will continue to use sound science in the decision-making process under our pesticides programs and to implementing those programs within their statutory requirements as written by Congress.

While traditional pest control involves the routine application of pesticides, IPM focuses on pest prevention and only using pesticides as needed. This provides a more effective, environmentally sensitive approach that combines biological, cultural, physical, and chemical tools to minimize risks associated with pests and pesticides. Furthermore, IPM has the potential to reduce greenhouse gas emissions that contribute to climate change. IPM strategies often use fewer pesticides resulting in less fuel consumption for pesticide application.

9. Effective pest and rodent control is essential to protecting the health and well-being of our families and communities, regardless of socioeconomic circumstances. Mosquitoes, for example, can carry West Nile virus, Zika virus, Eastern Equine Encephalitis, and yellow fever. Ticks can carry Lyme disease and Rocky Mountain spotted fever. According to the CDC, rodents directly transmit eleven serious diseases (including Hantavirus pulmonary syndrome, plague, and tularemia), and indirectly transmit even more. Whether pest control is undertaken by a professional or a consumer, pesticide products are a crucial component of managing pests and protecting public health at home, school, work, and play. If confirmed, how would you promote greater efficiency in the Office of Pesticide Programs, so these essential products are effectively managed through the regulatory process that follows FIFRA's risk-benefit standards and fully considers the benefits of the non-agricultural pesticides used to control mosquitoes, ticks, rodents, termites, and plant diseases?

EPA response: Federal law requires EPA, in coordination with Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA), to identify pests of significant public health importance and in coordination with the Public Health Service, to

develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological, and other methods to combat and control such pests of public health importance. I believe it is vital to continue this work and to collaborate with the pest control industry and the environmental community to find common ground on protecting human health and the environment and controlling dangerous pests.

If confirmed, I look forward to working with the pest control industry and other stakeholder groups on how to chart a path forward. Because the public relies on EPA to pesticides to ensure they can be used effectively without posing unreasonable risks to human health and the environment, I want to work with stakeholders to gather the necessary data to inform our decision-making processes for pesticides, including for public health pesticides. As the Agency's career staff have responded in other public health emergencies, such as the current COVID-19 pandemic as well as the Zika and West Nile virus outbreaks, we will continue to prioritize reviews for pesticides to be used in these situations.

10. In November 2020, EPA released its draft Biological Evaluation (BE) for public comment on atrazine, simazine and propazine, three widely-used herbicides used to control a variety of grasses and broadleaf weeds. EPA's comment period closed in February 2021, but EPA has not yet published the final BE. If confirmed, what will you do to ensure all reliable and available science, with respect to both exposure and toxicity, is fully assessed and used to impact the final BE on this crucial technology product group?
    a. Further, if confirmed, what steps will you take to ensure full consideration is given to the data alluded to in the paper "Grounds for an Atrazine Ecological Endpoints Update," submitted to EPA by a group of farm organizations on December 15, 2020?

EPA Response: I I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting endangered species and supporting local agricultural economies. Biological evaluations are the beginning of EPA's Endangered Species Act consultation review process for pesticides where the agency determines if an endangered or threatened species or critical habitat could be affected by the use of a certain pesticide. After carefully considering the public comments and any additional data received, the agency intends to finalize the biological evaluation in late 2021. If EPA determines a pesticide may affect a listed species or its critical habitat, the agency will then consult with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Services) as appropriate. The Services will then issue a biological opinion to determine if the population of a species would be adversely impacted and, if so, propose ways to reduce risks. It is the goal of EPA to ensure that pesticides can continue to be used safely with minimal impacts to threatened and endangered species. We will consider all input received as we work to make any scientifically supportable changes to the biological evaluation prior to initiating consultation with the Services.

I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward. If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including our pesticides programs.

11. In addition to serving on EPW, I am also honored to serve as the Ranking Member on the Senate Agriculture, Nutrition & Forestry Committee, which has primary oversight over FIFRA and EPA's work related to pesticides. If confirmed, do you commit to appearing before the Senate Agriculture, Nutrition & Forestry Committee on issues related to EPA's administration and implementation of FIFRA-related activities?

EPA Response: Yes, if confirmed I would look forward to working with the Senate Agriculture Committee on pesticides issues.

Senator Wicker:

1. The Pesticide Registration Improvement Act (PRIA) was signed into law in 2004 and was reauthorized in 2007, 2012 and 2019, each time with the support of a diverse group of stakeholders. This legislation brought new, dedicated funds to the Environmental Protection Agency's (EPA) Office of Pesticide Programs for more efficient pesticide registration and re-registration activities. It also gave registrants certainty in the registration process after decades of uncertainty, and it provided funding for farm worker education and training. Due to resource constraints and other issues, the rate in renegotiated decision timeframes for pesticide regulatory reviews has jumped significantly in the past few years. Since the start of Fiscal Year 2021, EPA has renegotiated nearly 64% of all conventional pesticide decision deadlines, 24% of biopesticide decision deadlines, 6% of antimicrobial deadlines and over 28% of inert ingredient decision deadlines. In addition, there is a significant backlog of smaller non-PRIA actions that are paid for by annual registrant paid maintenance fees on existing products. If confirmed, will you work to enact process improvements to address the significant renegotiation rates and the backlog of non-PRIA actions?

    a. If confirmed, will you also continue the efforts of past Assistant Administrators and convene all stakeholders including Congress, industry and non-governmental organizations to reauthorize PRIA prior to the start of Fiscal Year 2024 to ensure EPA has the resources needed to complete timely pesticide registration and registration review decisions efficiently?

EPA response: I agree and, it confirmed, will continue efforts to work with stakeholders and Congress to provide technical assistance to support the successful reauthorization of PRIA, to ensure EPA has the needed resources to accomplish its mission, and provide a more predictable evaluation process for affected pesticide decisions. PRIA is vital to the agency, which not only authorizes the collection of fees for various pesticide registration actions, but also funds other stakeholder priorities, such as farm worker protection activities, partnership grants, and pesticide safety education programs.

2. EPA's pesticide evaluation process is science-based and considers both the potential risks and benefits of pesticide products. The registration process includes risk assessments to ensure that the product protects human health, including the health of children, the

elderly, and immune-compromised individuals, the environment, and endangered species. In addition, the law requires EPA to reevaluate all registered pesticides at least every 15 years to ensure they continue to meet required safety standards. The current review cycle concludes October 1, 2022. This robust-science based regulatory system is essential to providing consumers with assurance about the safety of pesticide products that are vital for protecting our nation's food supply, public health and safety, and natural resources. Our regulatory process also is considered the gold standard globally and is required to meet World Trade Organization obligations. If confirmed, how will EPA, under your leadership, strengthen and defend risk-based regulation and the science supporting its regulatory decisions?

EPA Response: I support EPA's risk-based approaches to pesticide assessments. EPA's risk-based approach to pesticide registration and reevaluation decisions considers both hazard and potential exposure, with a rigorous risk assessment and risk management process. To this end, EPA's continued work with Canada and Mexico, now under the USMCA agreement, is important in developing harmonized approaches across North America. Moreover, EPA continues to collaborate with international pesticide regulators on global joint reviews of new active ingredients and in other forums to understand and potentially resolve differences in assessment and regulatory approaches.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including our pesticides programs.

3. The 2018 Farm Bill directed EPA, the U.S. Fish and Wildlife Service, and the National Marine Fisheries Service to establish an Interagency Work Group to increase the timeliness and quality of Endangered Species Act (ESA) species and habitat consultations for pesticides. The legislation also required EPA and the Services to develop a streamlined process for identifying which actions require consultations and to secure durable cooperation between the agencies. In recent public statements, you have mentioned that fixing the alignment of the Endangered Species Act and FIFRA is essential, and the ability of EPA to approve new crop protection products is at risk to be shut down by the courts if not fixed. If confirmed, do you commit to working with your colleagues at the U.S. Fish and Wildlife Service and the National Marine Fisheries Service to avoid a programmatic stoppage?

EPA Response: I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting endangered species and supporting local agricultural economies.

However, we also need to make further progress in making endangered species effects determinations in a more efficient manner and based on sound science. While we will continue to work and consult with the Services, as appropriate, and meet our litigation related commitments, EPA is pivoting in an effort to identify and implement protections for listed species earlier in the pesticide registration process. To that end, EPA is interested in working

with its stakeholders, particularly the registrants and growers, to identify mitigations for protecting species in the short term. Also, the Agency believes that this is an area where the idea of conservation measures might be helpful. I have also encouraged pesticide manufacturers to continue efforts to develop newer reduced risk chemistries and challenged them to actively consider environmental effects to endangered species as part of the process. EPA is committed to working with its stakeholders to realize our shared goal of protecting vulnerable species in a manner that is both effective and practical and ensures the availability and benefits of pesticides. If confirmed, I look forward to working with the agricultural community and other stakeholder groups on how to chart a path forward.

Senator Ernst:

1. You have spoken about your commitment to scientific integrity. I applaud your focus on that; it is indeed critical to ensure that every decision EPA makes is based on sound science. I know you also understand as well as anyone that the regulation of pesticides in this country is risk-based, and that FIFRA, the primary law governing pesticide regulation, also requires EPA to balance any risks of a pesticide with its benefits. There is a class of selective herbicides that cattle producers and other land managers in my state and across the country have used successfully for decades to manage noxious/invasive weeds and improve pasture/rangeland health. EPA has recently published decisions/proposals involving products in this class of chemicals that show a pretty striking overemphasis on a very narrow set of potential hazards/perceived risks related to agricultural waste and its use in compost and a woefully insufficient regard for the very real benefits of the products in question, including the many risks that pesticide products reduce or eliminate. I'm concerned that without a course correction, cattle producers in my state and across the country may lose the flexibility they need to use these products. I'm especially concerned that the direction EPA is going could limit cattle producers' options during times of drought or other natural disasters – threatening not only their bottom line but the welfare of their animals. Decisions that rely on sound science incorporate all available information, including the considerable benefits from pesticides, and rely on data to assess risk, not inaccurate default assumptions. How will you improve the quality of EPA's pesticide reviews to more accurately reflect the underlying science on a pesticide product's benefits and risks?

EPA Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward.

Regarding your concern about EPA pesticide decisions limiting cattle producers' option, if confirmed, I look forward to working with the agricultural community and other stakeholder groups on how to chart a path forward. I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting human health and the environment and supporting local agricultural economies. Regarding the specific issue of certain herbicides used by cattle producers, it is my understanding that some of these chemicals can persist in treated plant materials, and when treated materials are recycled into compost, can cause harm to plants in gardens and ornamental plots where the compost is applied. As a result, and in order to keep this tool for cattle producers, in 2020 the agency began the

process to put certain restrictions in place for this class of herbicides such as prohibiting the transport of treated plant matter and manure from animals that recently grazed in treated areas for offsite composting for a period of time until these pesticide residues have adequately declined.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including using the best available science.

2. Pesticides are of critical importance to agriculture and enable a safe and reliable food supply. EPA's pesticide registration process is a long-standing, efficient process that has garnered bipartisan support regardless of administration for enabling responsible pesticide use. Managing this program effectively means ensuring that farmers and ranchers have the crop protection tools they need. How do you plan to manage this program and do you anticipate any major changes to the program?

EPA Response: I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting human health and the environment and supporting local agricultural economies.

I also believe that restoring trust that the Agency's pesticide safety activities are grounded in sound science and the law benefits agricultural stakeholders. In the recent past, Courts have rejected EPA pesticide actions in part because of the Agency's failure to adequately consider key data. These events did not just result in the inability of agricultural stakeholders to use important pesticide tools, but also eroded public confidence. When the public trusts the Agency's statements about how pesticides can be used safely, the public will also have increased confidence in the products agricultural stakeholders make and use.

If confirmed, I look forward to working with the agricultural community and other stakeholder groups on how best to manage EPA's pesticides programs.